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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,590	11/21/2001	Nam Joong Kim	P67297US0	2462

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/926,590	Applicant(s) KIM ET AL.	
	Examiner Liliana Di Nola-Baron	Art Unit 1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 15-27.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because:

Applicant's argument have been fully considered, but they have been found not persuasive.

Applicant argues that wax is not a lubricant. This argument has been found persuasive, however, U.S. Patent 5,520,927 teaches that the compositions of the invention comprise lecithin (See Example 1), PEG-lanolin (See Example 14) or Arlacel 165 (See Example 15), and said compounds are lubricants.

With regard to the amount of somatropin claimed in claim 17, the patent teaches that 161.8 mg of mixture contain 100 mg of somatropin (See Example 1), corresponding to an amount of 61.8% by weight, thus the patent discloses compositions comprising a concentration of somatropin even higher than the concentration claimed by Applicant.

In response to Applicant's argument, that the object of the patent is different from the object of the present invention, it is noted that Applicant's invention is directed to composition claims, and feature intended use has no patentable weight in composition claims.

In response to Applicant's argument, that the composition of the instant application is prepared by a method, which is different from the method disclosed in the patent, it is noted that Applicant is not claiming a product by process.

In response to Applicant's argument, that the syringeability of the compositions disclosed by the patent is worse than the one of the compositions claimed by Applicant, it is noted that the instant claims do not read on the syringibility of the compositions.

Applicant argues that the object of U.S. Patent 6,497,886 is different from Applicant's claimed invention. In response to said argument, it is noted that feature intended use has no patentable weight in composition claims.

In response to Applicant's argument, that the patent discloses additional ingredients, the burden is shifted to Applicant to show that said additional ingredients would be detrimental to the composition as claimed.

In response to Applicant's argument, that the prior art teaches solutions, whereas the instant application is directed to suspensions, it is noted that the instant claims do not read on suspensions.

With respect to the lubricant, the patent discloses PEG-stearate and cetyl palmitate (See Example 12), which are esters of a fatty acid and an alcohol.

In response to Applicant's argument, that the amendment was only editorial and did not require any new grounds of rejection, it is noted that the new grounds of rejection were only limited to the change in claim number prompted by Applicant's amendment.

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